MAY 1 8 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HARTLEY et al.

Appl. No.: 09/517,466

Filed: March 2, 2000

For: Compositions and Methods for Use In Recombinational Cloning of

**Nucleic Acids** 

Confirmation No.: 4289

Art Unit:

1634

Examiner:

Johannsen, D.B.

Atty. Docket: 0942.4680003/BJD/JKM

Tenth Supplemental Information Disclosure Statement

Under 37 C.F.R. § 1.97(c)

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Tenth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Ninth Supplemental Information Disclosure Statement filed on February 9, 2005 in connection with the above-captioned application.

Copies of documents AM23 to AM24 and AT216 to AR228 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents AH21 to AK24, cited on the attached IDS Form, PTO/SB/08A, are not submitted. In addition, copies of documents AS228, AT228 and AR229 are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii)

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for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is sua sponte waived where the cited pending application is stored in the USPTO's IFW system."

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document AR219 cited on PTO/SB/08B:

Document AR219, Gotou, N., et al., "Gateway, Cloning Technology," Exp. Med. Sci. 18:2716-2717, Invitrogen Corporation (December 2000), is in the Japanese language. An unverified English language translation of document AR219 is attached as document AS219.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

Application No. 11/106,715, Byrd *et al.*, filed April 15, 2005 and listed as Document **AS228**; and

Application No. 11/290,804, Gray et al., filed December 1, 2005 and listed as Document AT228.

Application No. 10/633,690, Byrd *et al.*, filed August 5, 2003 and listed as Document **AR229**.

In accordance with the recent Federal Circuit decision in *Dayco Prods., Inc. v.*Total Containment, Inc. 329 F.3d 1358 (Fed. Cir. 2003), Applicants submit herewith

Office Actions from:

the related co-pending U.S. Patent Application No. 09/432,085, Hartley et al, as Documents AT223 and AR224;

the related co-pending U.S. Patent Application No. 09/855,797, Hartley *et al*, as Documents **AS224** and **AT224**;

the related co-pending U.S. Patent Application No. 09/907,719, Hartley et al, as Documents AR225 and AS225;

the related co-pending U.S. Patent Application No. 10/058,291, Hartley *et al*, as Documents **AT225** and **AR226**;

the related co-pending U.S. Patent Application No. 10/058,292, Hartley *et al*, as Documents **AS226** and **AT226**;

the related co-pending U.S. Patent Application No. 10/151,690, Brasch *et al*, as Document AR227;

the related co-pending U.S. Patent Application No. 10/162,879, Hartley  $et\ al$ , as Documents AS227 and AT227; and

the related co-pending U.S. Patent Application No. 10/796,868, Hartley *et al*, as Document **AR228**;

which are directed to related technical subject matter. The identification of these applications and Office Actions is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038

Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Jeffrey K. Mills

Agent for Applicants Registration No. 56,413

Date:

May 18,2016

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600 525864v1

Equivalent of Form PTO/SB/08A (07-05)

0942.4680003/BJD/JKM

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE MAY 1 8 2006 of 1995, no negon Under the Paperwork Reduction uired to respond to a collection of information unless it contains a valid OMB control number.

Pade Mication Number Substitute for form 1449/PTO Complete if Known 09/517,466 TENTH SUPPLEMENTAL March 2, 2000 INFORMATION DISCLOSURE First Named Inventor James L. HARTLEY STATEMENT BY APPLICANT Art Unit 1634 (Use as many sheets as necessary) **Examiner Name** Johannsen, D.B.

Attorney Docket Number

Sheet

of

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			U.S. PATENT DO	OCUMENTS	
Examiner Initials	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
initiais	140.	Number-Kind Code <sup>2 (If Known)</sup>	IVIIVI-DB-1111	Applicant of Cited Document	or Relevant Figures Appear
	AH21	5,552,314	09/03/1996	Greener	
	AI21	5,695,971	12/09/1997	Kadokami et al.	
	AJ21	5,910,438	06/08/1999	Bernard et al.	
	AK21	5,994,136	11/30/1999	Naldini et al.	
	AA22	6,025,192	02/15/2000	Beach et al.	
	AB22	6,040,138	03/21/2000	Lockhart et al.	
	AC22	6,110,735	08/29/2000	Chartier et al.	
	AD22	6,120,764	09/19/2000	Graham et al.	
	AE22	6,121,043	09/19/2000	Cochran et al.	
	AF22	6,140,087	10/31/2000	Graham et al.	
•	AG22	6,156,497	12/05/2000	Kaleko	
	AH22	6,165,782	12/26/2000	Naldini et al.	
	AI22	6,228,646	05/08/2001	Hardy	
	AJ22	6,281,000	08/28/2001	Chartier et al.	
	AK22	6,303,301	10/16/2001	Mack	
	AA23	6,309,822	10/30/2001	Fodor et al.	
	AB23	6,333,155	12/25/2001	Lockhart et al.	
•	AC23	6,544,790	04/08/2003	Sabatini	
-	AD23	6,576,463	06/10/2003	Kasahara et al.	
	AE23	6,964,861	11/15/2005	Gerard et al.	

		Fo	REIGN PATENT DO	OCUMENTS	
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			T <sup>6</sup>
	AM23	WO 96/23904 A1	08/08/1996	Replicon, Inc.	
	AN23	WO 97/47758 A1	12/18/1997	Massachusetts Institute of Technology	
	AO23	WO 98/38326 A1	09/03/1998	Nature Technology Corporation	
		WO 01/68836	09/20/2001	Genetica, Inc. and Cold Spring Harbor	
	AP23			Laboratory	
	AL24	WO 2005/012487 A2	02/10/2005	Invitrogen Corporation	
	AM24	WO 2005/014796 A2	02/17/2005	Invitrogen Corporation	
		<u> </u>			

Examiner	Date
Signature	Considered

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute	for form	1449/PT	0	Complete if Known		
are star	II OII	nni r	NATURATURA Y	Application Number	09/517,466	
			MENTAL	Filing Date	March 2, 2000	
			DISCLOSURE	First Named Inventor	James L. HARTLEY	
STAT			APPLICANT	Art Unit	1634	
	(Use as	many she	eets as necessary)	Examiner Name	Johannsen, D.B.	
Sheet	2	of	2	Attorney Docket Number	0942.4680003/ВЈD/ЈКМ	

			U.S. PATENT DO		
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
IIIIIIII		Number-Kind Code <sup>2 (If Known)</sup>		•	or Relevant Figures Appear
	AF23	2002/0162126 A1	10/31/2002	Beach et al.	
	AG23	2003/0022179 A1	01/30/2003	Chesnut et al.	
	AH23	2003/0100110 A1	05/29/2003	Hartley et al.	
	AI23	2003/0135888 A1	07/17/2003	Zhu et al.	
	AJ23	2003/0175772 A1	09/18/2003	Wang, Jiwu	
	AK23	2004/0132133 A1	07/08/2004	Bennett, Robert P.	
	AA24	2004/0229229 A1	11/18/2004	Cheo et al.	
	AB24	2004/0253620 A1	12/16/2004	Leong et al.	
	AC24	2004/0265863 A1	12/30/2004	Chesnut et al.	
	AD24	2005/0009091 A1	01/13/2005	Hartley et al.	
	AE24	2005/0069929 A1	03/31/2005	Chestnut et al.	
	AF24	2005/0095615 A1	05/05/2005	Welch et al.	
	AG24	2005/0176065 A1	08/11/2005	Hanson, George Thomas	
	AH24	2005/0181417 A1	08/18/2005	Miles et al.	
	AI24	2005/0208530 A1	09/22/2005	Chesnut et al.	
	AJ24	2006/0035269 A1	02/16/2006	Hartley et al.	
	AK24	2006/0035272 A1	02/16/2006	Brasch et al.	

			FOREIGN PATENT DOCUME	NTS	
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	
Initials*	No.1	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	T <sup>6</sup>

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Substitute for	form 1449/P7	го		Co	mplete if Known
	CLIDDL E	an eran	7/ED A. W.	Application Number	09/517,466
TENTH				Filing Date	March 2, 2000
INFORMATION DISCLOSURE				First Named Inventor	James L. HARTLEY
STATE			PLICANT	Art Unit	1634
	(Use as many	sheets a	s necessary)	Examiner Name	Johannsen, D.B.
Sheet	1	of	4	Attorney Docket Number	0942.4680003/BJD/JKM

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AT216	Alonso, J.C., "Site-specific recombination in Gram-positive theta-replicating plasmids," <i>FEMS Microbiol. Lett.</i> 142:1-10, Elsevier Science B.V. (1996)	
	AR217	Amin, A.A., et al., "Synthesis of an Enzymatically Active FLP Recombinase In Vitro: Search for a DNA-Binding Domain," Molec. Cell. Biol. 9: 1987-1995, American Society for Microbiology (1989)	
	AS217	Aoki, K., et al., "Efficient Generation of Recombinant Adenoviral Vectors bt Cre-lox Recombination In Vitro," Molec. Med. 5:224-231, Springer (April 1999)	
	AT217	Baum, J.A., "Tn5401, a New Class II Transposable Element from Bacillus thuringiensis," J. Bacteriol. 176:2835-2845, American Society for Microbiology (1994)	
	AR218	Bliska, J.B and Cozzarelli, N.R., "Use of Site-Specific Recombination as a Probe of DNA Structure and Metabolism in Vivo," J. Molec. Biol. 194:205-218, Academic Press Inc. (1987)	
	AS218	Carninci, P. and Hayashizaki, Y., "High-Efficiency Full-Length cDNA Cloning," Meth. Enzymol. 303:19-44, Academic Press (May 1999)	
	AT218	Chatterjee, P.K. and Sternberg, N.L., "Retrofitting High Molecular Weight DNA Cloned in P1: Introduction of Reporter Genes, Markers Selectable in Mammalian Cells and Generation of Nested Deletions," <i>Genet. Anal.: Biomolec. Eng. 13</i> :33-42, Elsevier Science B.V. (1996)	
	AR219	Gotou, N., et al., "Gateway, Cloning Technology," Exp. Med. Sci. 18:2716-2717, Invitrogen Corporation (December 2000)	Yes
	AS219	English language translation for Gotou, N., et al., "Gateway, Cloning Technology," Exp. Med. Sci. 18:2716-2717, Invitrogen Corporation (December 2000)	
	AT219	Huang, LC., et al., "A bacterial model system for chromosomal targeting," Nucl. Acids Res. 19:443-448, Oxford University Press (1991)	
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	Examiner	Date	
ı	Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for	Substitute for form 1449/PTO			Complete if Known		
	CLIDDL	7 B # T7 B	I'E A T	Application Number	09/517,466	
TENTH SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	March 2, 2000	
1				First Named Inventor	James L. HARTLEY	
STATE			PLICANT	Art Unit	1634	
	(Use as many sheets as necessary)		Examiner Name	Johannsen, D.B.		
Sheet	2	of	4	Attorney Docket Number	0942.4680003/BJD/JKM	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	AR220	Kanegae, Y., et al., "Efficient gene activation in mammalian cells by using recombinant adenovirus expressing site-specific Cre recombinase," Nucl. Acids Res. 23:3816-3821, Oxford University Press (1995)	
	AS220	Kijima, T., et al., "Application of the Cre Recombinase/loxP System Further Enhances Antitumor Effects in Cell Type-specific Gene Therapy against Carcinoembryonic Antigen-producing Cancer," Canc. Res. 59:4906-4911, American Association for Cancer Research, Inc. (October 1999)	
	AT220	Lieber, A., et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre- Mediated Excision Exhibit Different Biological Properties Compared with First- Generation Vectors In Vitro and In Vivo," J. Virol. 70:8944-8960, American Society for Microbiology (1996)	
	AR221	Liu, X. and Gorovsky, M.A., "Mapping the 5' and 3' Ends of Tetrahymena thermophelia mRNAs Using RNA Ligase Mediated Amplification of cDNA Ends (RLM-RACE),"  Nucl. Acids Res. 21:4954-4960, Oxford University Press (1993)	
	AS221	NCBI Entrez, Genbank Report, Accession No. Y08806, Zucman-Rossi, J., et al., (first available November 1996 and last updated April 2005)	
	AT221	Ng, P., et al., "A High-Efficiency Cre//loxP-Based System for Construction of Adenoviral Vectors," Human Gene Ther. 10:2667-2672, Mary Ann Liebert, Inc. (November 1999)	
	AR222	Short, J.M., et al., "λ ZAP: a bacteriophage λ expression vector with in vivo excision properties," Nucl Acids Res. 16:7583-7600, IRL Press Ltd. at Oxford University Press (1988)	
	AS222	Walhout, A.J.M., et al., "Protein Interaction Mapping in C. elegans Using Proteins Involved in Vulval Development," Science 287:116-122, American Association for the Advancement of Science (January 2000)	_
	AT222	Walhout, A.J.M., et al., "GATEWAY Recombinational Cloning: Application to the Cloning of Large Numbers of Open Reading Frames or ORFeomes," Meth. Enzymol. 328:575-592, Academic Press (September 2000)	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

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CONSTRUCT CLIPPL ENGENIES AT			1757 A W	Application Number	09/517,466		
TENTH SUPPLEMENTAL		Filing Date	March 2, 2000				
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				First Named Inventor	James L. HARTLEY		
				Art Unit	1634		
(Use as many sheets as necessary)		Examiner Name	Johannsen, D.B.				
Sheet	3	of	4	Attorney Docket Number	0942.4680003/BJD/JKM		

		Non Patent Literature Documents	
Examiner Initials*			T <sup>2</sup>
	AR223	Wang, Y. et al., "Targeted DNA recombination in vivo using an adenovirus carrying the cre recombinase gene," Proc. Natl. Acad. Sci. USA 93:3932-3936, National Academy of Sciences (1996)	!
	AS223	Zucman-Rossi, J., et al., "Chromosome translocation based on illegitimate recombination in human tumors," Proc. Natl. Acad. Sci. USA 95:11786-11791, National Academy of Sciences (September 1998)	
	AT223	Copy of Office Action for United States Patent Application No. 09/432,085, Hartley et al., mailed December 28, 2004	
	AR224	Copy of Office Action for United States Patent Application No. 09/432,085, Hartley et al., mailed June 16, 2005	
	AS224	Copy of Office Action for United States Patent Application No. 09/855,797, Hartley et al., mailed April 20, 2005	
	AT224	Copy of Office Action for United States Patent Application No. 09/855,797, Hartley et al., mailed October 11, 2005	
	AR225	Copy of Office Action for United States Patent Application No. 09/907,719, Hartley et al., mailed December 28, 2004	,
	AS225	Copy of Office Action for United States Patent Application No. 09/907,719, Hartley et al., mailed July 26, 2005	
	AT225	Copy of Office Action for United States Patent Application No. 10/058,291, Hartley et al., mailed April 28, 2005	
	AR226	Copy of Office Action for United States Patent Application No. 10/058,291, Hartley et al., mailed October 21, 2005	

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	Examiner	Date	
	Signature	Considered	

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TOTAL CLUBBY ENGINE AT			TOPO A. W.	Application Number	09/517,466	
TENTH SUPPLEMENTAL				Filing Date	March 2, 2000	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				First Named Inventor	James L. HARTLEY	
				Art Unit	1634	
(Use as many sheets as necessary)		Examiner Name	Johannsen, D.B.			
Sheet	4	of	4	Attorney Docket Number	0942.4680003/BJD/JKM	

		NON PATENT LITERATURE DOCUMENTS			
Examiner Cite No. 1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			
	AS226	Copy of Office Action for United States Patent Application No. 10/058,292, Hartley et al., mailed May 26, 2005			
	AT226	Copy of Office Action for United States Patent Application No. 10/058,292, Hartley et al., mailed November 18, 2005			
	AR227	Copy of Office Action for United States Patent Application No. 10/151,690, Brasch et al., mailed April 18, 2005			
	AS227	Copy of Office Action for United States Patent Application No. 10/162,879, Hartley et al., mailed April 28, 2005			
	AT227	Copy of Office Action for United States Patent Application No. 10/162,879, Hartley et al., mailed October 20, 2005			
	AR228	Copy of Office Action for United States Patent Application No. 10/796,868, Hartley et al., mailed January 25, 2005			
	AS228	United States Patent Application No. 11/106,715, Byrd et al., filed April 15, 2005			
	AT228	United States Patent Application No. 11/290,804, Gray et al., filed December 1, 2005			
	AR229	United States Patent Application No. 10/633,690, Byrd et al., filed August 5, 2003			

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